DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

#28

DEC 28 1999

Re: Meridia®
Docket No. 98E-0755

The Honorable Q. Todd Dickinson
Deputy Assistant Commissioner for
Patent Policy and Projects
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, DC 20231

Dear Commissioner Dickinson:

This is in regard to the patent term extension application for U.S. Patent No. 4,746,680 filed by Knoll Aktiengesellschaft under 35 U.S.C. § 156. The patent claims the human drug product Meridia® (sibutramine hydrochloride monohydrate), new drug application NDA 20-632.

In the December 28, 1998, issue of the Federal Register (63 Fed. Reg. 71493), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before June 28, 1998, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Charles E. Van Horn, Esq.
Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P.
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Washington, DC 20005-3315

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